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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,661	10/17/2005	Kenneth Kao	50680-6 /slr	4668

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,661	KAO ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10, 31, 39, 40 and 46-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-4, 6-10, 31, 39, 40, 46-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

A preliminary amendment was received on 10/17/05. Claims 5, 11-30, 32-38, and 41-45 were canceled, and claims 54-56 were added. Claim 1-4, 6-10, 31, 39, 40, and 46-56 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-4, 6, and 7 in part and 8 in full, drawn to methods of determining the presence or absence of a cancer in a patient, the method comprising the steps of: (a) determining the level of Pygopus mRNA expression in a biological sample obtained from a patient, and (b) comparing the level of Pygopus mRNA expression in the biological sample to a predetermined cut-off value, to determine whether Pygopus expression is higher in the biological sample; therefrom determining the presence or absence of cancer in the patient.

Group 2, claim(s) 1-4, 6, 7, and 10 in part, and 9 in full, drawn to methods of determining the presence or absence of a cancer in a patient, the method comprising the steps of: (a) determining the level of Pygopus protein expression in a biological sample obtained from a patient, and (b) comparing the level of Pygopus protein expression in the biological sample to a predetermined cut-off value, to determine whether Pygopus expression is higher in the biological sample; therefrom determining the presence or absence of cancer in the patient.

Group 3, claims 10, 46, and 50-53, drawn to an oligonucleotide which is an antisense oligonucleotide, a short interfering RNA (siRNA) or a siRNA-like molecule, targeted to hPygo2 (SEQ ID NO:1) in the region from nucleotide 437 to 1156 of SEQ ID NO:1, wherein said antisense oligonucleotide, siRNA or siRNA-like molecule specifically hybridizes with said region and reduces the expression of hPygo2.

Group 4, claims 10 and 47, drawn to an oligonucleotide which is an antisense oligonucleotide, a short interfering RNA (siRNA) or a siRNA-like molecule, targeted to

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hPygo1 (SEQ ID NO:3) in the region from nucleotide 253 to 1023 of SEQ ID NO:3, wherein said antisense oligonucleotide, siRNA or siRNA-like molecule specifically hybridizes with said region and reduces the expression of hPygo 1.

Group 5, claim 31, drawn to a method of obtaining a compound which inhibits tumor cell proliferation, wherein the tumor cell express Pygopus, the method comprising: (a) delivering the oligonucleotide of claim 46 into epithelial ovarian carcinoma or breast cancer cells; and (b) determining whether the delivered oligonucleotide inhibits proliferation of the cancer cells.

Group 6, claim 54, drawn to a method of obtaining a compound which inhibits tumor cell proliferation, wherein the tumor cell express Pygopus, the method comprising: (a) delivering the oligonucleotide of claim 47 into epithelial ovarian carcinoma or breast cancer cells; and (b) determining whether the oligonucleotide inhibits proliferation of the cancer cells.

Group 7, claims 55 and 56, drawn to methods of inhibiting tumor cell proliferation, the method comprising delivering to the tumor cell a proliferation-inhibiting amount of the an oligonucleotide which reduces expression of a Pygopus-encoding nucleic acid wherein the oligonucleotide is an antisense oligonucleotide, a short interfering RNA (siRNA) or a siRNA-like molecule, targeted to hPygo1 (SEQ ID NO:3) in the region from nucleotide 253 to 1023 of SEQ ID NO:3, wherein said antisense oligonucleotide, siRNA or siRNA-like molecule specifically hybridizes with said region and reduces the expression of hPygo 1.

The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking inventions 1-7 is simply "Pygopus". However, Pygopus was known in the prior art (see e.g. Thompson et al (Nature Cell Biol. 4: 367-373, 2002) IDS reference C76). Moreover, the technical feature linking inventions 3-7 is an oligonucleotide targeted to Pygopus mRNA, and this technical feature is anticipated by Brennan (US Patent 5,474,796). Brennan taught an array of isolated oligonucleotides comprising every conceivable 10mer oligonucleotide sequence. See column 9, lines 48-55. Thus Brennan taught oligonucleotides that specifically hybridize with any sequence in SEQ ID NO:1 or 3. The functionality of reducing expression of hPygo1 or hPygo2 is considered to be inherent in the claimed structure. Because there is no special technical feature linking the inventions restriction between them is proper.

Should Applicant elect group 3, a further election of an oligonucleotide is required. Claims 50-53 recite oligonucleotide SEQ ID NOS: 5-19. Each of these oligonucleotides is considered to be an independent and distinct invention. Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that

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utility. Although the claimed sequences are oligonucleotides that target and modulate expression of the same mRNA, the claimed oligonucleotides are considered to be unrelated, since each oligonucleotides claimed is structurally and functionally independent because each oligonucleotides has a unique nucleotide sequence and targets a different and specific region of the mRNA. As such the claimed sequences are not considered to constitute a proper genus, and are therefore subject to restriction. Accordingly, If Applicant elects group 3, then a further election of one (1) of the oligonucleotides disclosed in the specification is required. Note that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
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